

Remarks

Claims 58-75 are pending in this application.

Obviousness-type Double Patenting

The Examiner provisionally rejected claims 58 and 61-66 under the doctrine of obviousness-type double patenting over claims 24-31 of co-pending U.S. Patent Application No. 10/263,518. Upon the identification of otherwise allowable subject matter, Applicants reserve their right to offer a terminal disclaimer to cure any remaining obviousness-type double patenting rejection.

Objections

The Examiner has objected to claims 59-60 and 62 as lacking antecedent basis for the phrase “the barrier layer.” The Applicants have amended claim 58 to correct the antecedent basis.

Rejection under 35 USC 102(e)

Claims 58-75 are rejected under 35 USC 102(e) as being anticipated by U.S. Patent No. 6,585,683 (Dischler). The Examiner states that Dischler teaches “polymers for the lamina, all of which are substantially water-impermeable (liquid and vapor) and thus will also be impermeable to gaseous ethylene oxide, as an ethylene oxide molecule is larger than a water molecule.” Applicants respectfully disagree.

First, applicants note that the permeability of a polymer to water (in liquid or vapor form) is not an indication of that polymer’s permeability to ethylene oxide. As recited on page 10, lines 13-23, containers impermeable to the elements of the container, such as skin antiseptic compositions, may still be permeable to ethylene oxide:

Among the challenges associated with using such skin antiseptic compositions is the need to sterilize the exterior of the applicator while minimizing potential byproducts that may be produced when the composition is exposed to sterilization compounds such as ethylene oxide gas. Reactive sterilants such as ethylene oxide may react with the active antimicrobial agent or with other components in the skin antiseptic composition altering the potency or producing potentially toxic compounds. For example, typical high density polyethylene bottles having wall thicknesses of less than about 500 micrometers allow ethylene oxide through quite readily and result in iodophor preps having iodohydrin levels of 100 parts per million (ppm) or more, in some

instances 200 ppm or more, and in some instances even as high as 600 ppm.

Dischler fails to teach any characteristics of the recited polymers that indicate its permeability to ethylene oxide. As demonstrated in Example 7 of Applicants' Specification, a polyethylene container with a barrier layer of polyester can reduce the levels of ethylene oxide and ethylene oxide byproducts by up to 87% compared to polyethylene containers without a barrier layer.

The Examiner rejects claim 61 under 35 USC 102(e) but acknowledges that Dischler fails to teach the skin antiseptic compositions recited in claim 61. Applicants note that Dischler teaches a syringe for injecting "medicaments." Skin antiseptic compositions are not injected into the skin.

For at least the above reasons, applicants respectfully submit that the rejection under 35 USC 102(e) should be withdrawn.

Conclusion

All outstanding objections and rejections are believed to have been met and overcome. If a telephonic conference with Applicants' undersigned representative would be useful in advancing the prosecution of the present application, the Examiner is invited to contact the undersigned at (651) 733-2180. A notice of allowance for all pending claims is respectfully solicited.

Respectfully submitted,

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